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health care entities that are under common control;

(5) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons;

(6) The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug under a prescription executed in accordance with section 503(b) of the act;

(7) The distribution of drug samples by manufacturers' and authorized distributors' representatives;

(8) The sale, purchase, or trade of blood or blood components intended for transfusion;

(9) Drug returns, when conducted by a hospital, health care entity, or charitable institution in accordance with §203.23; or

(10) The sale of minimal quantities of drugs by retail pharmacies to licensed practitioners for office use.

(dd) *Wholesale distributor* means any person engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.

[64 FR 67756, Dec. 3, 1999]

EFFECTIVE DATE NOTE: At 64 FR 67756, Dec. 3, 1999, §203.3 was added, effective Dec. 4, 2000. At 65 FR 25639, May 3, 2000, the effective date for §203.3(u) was delayed until Oct. 1, 2001. At 66 FR 12851, Mar. 1, 2001, §203.3(u) was further delayed until Apr. 1, 2002. At 67 FR 6646, Feb. 13, 2002, the effective date was further delayed until Apr. 1, 2003. At 68 FR 4912, Jan. 31, 2003, the effective date was further delayed until Apr. 1, 2004. At 69 FR 8105, Feb. 23, 2004, the effective date of §203.3(u) was further delayed until Dec. 1, 2006.

Subpart B—Reimportation

§203.10 Restrictions on reimportation.

No prescription drug or drug composed wholly or partly of insulin that was manufactured in a State and exported from the United States may be reimported by anyone other than its manufacturer, except that FDA may grant permission to a person other than the manufacturer to reimport a prescription drug or insulin-containing drug if it determines that such reimportation is required for emergency medical care.

§203.11 Applications for reimportation to provide emergency medical care.

(a) Applications for reimportation for emergency medical care shall be submitted to the director of the FDA District Office in the district where reimportation is sought (addresses found in part 5, subpart M of this chapter).

(b) Applications for reimportation to provide emergency medical care shall be reviewed and approved or disapproved by each district office.

[64 FR 67756, Dec. 3, 1999, as amended at 69 FR 17292, Apr. 2, 2004]

§203.12 An appeal from an adverse decision by the district office.

An appeal from an adverse decision by the district office involving insulin-containing drugs or prescription human drugs, other than biological products, may be made to the Office of Compliance (HFD–300), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. An appeal from an adverse decision by the district office involving prescription human biological products may be made to the Office of Compliance and Biologics Quality (HFM–600), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852 or the Office of Compliance (HFD–300), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, depending on the Center responsible for regulating the product.

[64 FR 67756, Dec. 3, 1999, as amended at 69 FR 48775, Aug. 11, 2004; 70 FR 14980, Mar. 24, 2005]

Subpart C—Sales Restrictions

§203.20 Sales restrictions.

Except as provided in §203.22 or §203.23, no person may sell, purchase,